



**Testimony
Before the Committee on Health,
Education, Labor, and Pensions
United States Senate**

**CDC Food Safety Activities and the
Recent *E.coli* Spinach Outbreak**

Statement of

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Introduction

Good afternoon, Chairman Enzi and Members of the Subcommittee. I am Lonnie King, the Centers for Disease Control and Prevention's (CDC) senior veterinarian, and I am leading the effort to form a new center at CDC focusing on zoonotic, vector-borne, and enteric diseases, which includes CDC's foodborne illness related activities.

Accompanying me today is Dr. Chris Braden, Chief of the Outbreak Response and Surveillance Team for our foodborne illness activities. Thank you for the invitation to address the subcommittee on CDC's activities related to foodborne illness in general and on CDC's role in the response to the recent outbreak of *E. coli* infections associated with fresh spinach.

Background

Many people do not think about food safety until a food-related illness affects them or a family member. CDC estimates that 76 million people get sick, more than 300,000 are hospitalized, and 5,000 Americans die each year from foodborne illness. Preventing foodborne illness remains a major public health challenge.

More than 250 different foodborne illnesses have been described in scientific literature. Most of these diseases are caused by a variety of bacteria, viruses, and parasites. Some foodborne illnesses are poisonings, caused by harmful toxins or chemicals that have contaminated the food such those found in as poisonous mushrooms. These various illnesses have many different clinical signs, and therefore they cannot be characterized as one foodborne illness "syndrome."

Microbes spread in a variety of ways, so it is not always certain that an identified illness is caused by food. In order to prevent and control illness, public health authorities need to determine how a particular disease is spreading. For example, *Escherichia coli* (*E. coli*) O157:H7 infections can spread through contaminated food, contact with infected petting zoo animals, contaminated swimming water, and from toddler to toddler at a child-care center. Depending on transmission routes, the measures to stop other cases from occurring might involve removing contaminated food from stores, chlorinating a swimming pool, or closing a child-care center. By conducting a rapid investigation, epidemiologists and laboratorians can determine the source of an outbreak and recommend immediate measures to control it. Detailed investigations into how contamination occurs are critical to developing strategies to prevent similar outbreaks in the future.

Many foodborne infections occur separately without obvious connection to other cases. These are called sporadic cases. Determining the source of a single sporadic case can be very difficult. Cases of similar infections can also occur as a group or “cluster.” Epidemiological investigation of clusters of possibly related cases permits public health officials to determine if the cases are linked to food, which is the first step in preventing further illnesses. An outbreak of foodborne illness is considered a cluster if two or more infections caused by the same agent (pathogen or toxin) are linked to the same food upon investigation. Roughly 1200 foodborne outbreak investigations are reported to CDC each year. CDC works closely with local and state health departments to investigate foodborne disease outbreaks and make information available to the public.

Produce-related outbreaks such as the recent outbreak associated with raw spinach have become larger and more common. For example, in the 1970s, foodborne outbreaks related to produce accounted for less than 1% of outbreaks with a known food source. By the end of the 1990s, they accounted for 6% of these outbreaks.

CDC's Role in Preventing Foodborne Illness

As an agency within the Department of Health and Human Services (HHS), CDC leads federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts. CDC is not a food safety regulatory agency but works closely with the food safety regulatory agencies, in particular with HHS's Food and Drug Administration (FDA) and the Food Safety and Inspection Service within the United States Department of Agriculture (USDA). CDC also plays a key role in identifying prevention strategies and building state and local health department epidemiology, laboratory, and environmental health capacity to support foodborne disease surveillance and outbreak response. Notably, CDC data are used to help document the effectiveness of regulatory interventions.

In partnership with state health departments, CDC collects surveillance information on foodborne illness. The states collect data about cases of infections that are of public health importance from doctors and clinical laboratories. CDC helps states investigate outbreaks that are large, severe, or unusual. When a new problem emerges, as happened in 1982 when *E. coli* O157 was first recognized as a cause of human illness,

CDC conducts practical research to determine the best diagnostic methods and to define the source of the illness.

To initially make a diagnosis, a patient must seek medical attention, the physician must decide to order diagnostic tests, and the laboratory must use the appropriate procedures. Many ill people do not seek medical attention, and of those who do, many are not tested. Therefore, many cases of foodborne illness go undiagnosed and are not reported. For example, CDC estimates that 38 cases of salmonellosis occur for every case that is actually reported to CDC. Some foodborne infections are not identified by routine laboratory procedures and require specialized, experimental, and/or expensive tests that are not generally available. When there is an outbreak of illness and routine testing does not identify the microbe or other causes, samples from the patients may be sent to the state public health laboratory or to CDC for more specialized testing. Less than half of all foodborne outbreaks have known causes or etiology.

Surveillance and Epidemiology

CDC specializes in the critically important public health activities of surveillance, epidemiologic response, and investigation of disease. Routine disease surveillance systems coordinated by CDC, combined with CDC epidemiology offices and laboratories provide an essential early-information network to detect potential threats to the public in the food supply. These systems can be used to indicate new or changing patterns of foodborne illness.

In 1993, there was a large multi-state outbreak of *E. coli* O157 infections in the Western United States. In order to prevent future severe outbreaks by enabling rapid comparison of bacteria isolated from ill persons around the country, an effective surveillance network called PulseNet was developed. PulseNet is the national network for molecular subtyping of foodborne bacteria, which was developed in collaboration with the Association of Public Health Laboratories (APHL) and is coordinated by CDC. The laboratories participating in PulseNet are in state health departments, some local health departments, USDA, and FDA. PulseNet plays a vital role in surveillance for and investigation of foodborne illness outbreaks that were previously difficult to detect. For example, when a clinical laboratory diagnoses *E. coli* O157 in a patient, that bacterial strain is sent to the participating PulseNet laboratory where it is subtyped, or “DNA fingerprinted”. The “fingerprint” is then compared with other patterns in the state, and uploaded electronically to the national PulseNet database maintained at CDC, where it can be compared with the patterns in other states. This gives us the capability to rapidly detect a cluster of infections with the same pattern that is occurring in multiple states. The PulseNet database, which includes approximately 120,000 DNA patterns, is available to participating laboratories and allows them to rapidly compare patterns. Once a cluster of cases with the same DNA pattern is identified, epidemiologists then interview patients to determine whether cases of illness are linked to the same food source or other exposures they have in common. The strength of this system is its ability to identify patterns even if the affected persons are geographically far apart, which is important given the reality of U.S. food distribution systems. If patients have been exposed to a specific food or to another source of infection and the case count for

that illness is larger than one would expect for the time period, the cluster is determined to be an outbreak with a common source.

The group of epidemiologists in the states and at CDC who regularly investigate and report on these outbreaks is called OutbreakNet. The OutbreakNet participants use standardized interview methods and forms and rapidly share the investigation data. With this collaboration, outbreaks can be investigated in a matter of days rather than weeks. As a consequence, CDC can more rapidly alert FDA and USDA about implicated food products associated with foodborne illness so that all three agencies can collaboratively take actions to protect public health. Tracing the implicated food back from consumption through preparation, to distributors, and sometimes back to a field or farm can help determine how the contamination occurred, stop distribution of the contaminated product, and prevent further outbreaks from occurring. OutbreakNet and CDC's overall efforts to continuously improve methods and to train epidemiologists, laboratorians, and environmental health specialists are making investigations of outbreaks faster and more likely to identify the source. With this enhanced capacity, the public health system can rapidly identify implicated foods with precision and minimize the impact of the outbreak.

Another important surveillance network is CDC's Foodborne Diseases Active Surveillance Network (FoodNet). This network is a collaboration among ten state health departments, USDA, and FDA that closely monitors the human health burden of foodborne diseases in the United States. It produces reliable estimates of the burden and trends over time for foodborne infections of public health importance. In the

participating sites, FoodNet conducts active surveillance for foodborne diseases and also conducts related epidemiologic studies that look at sporadic and outbreak foodborne infections to help public health officials better understand the epidemiology of foodborne diseases in the United States and how to target prevention strategies. We have PulseNet to detect possible outbreaks, OutbreakNet to investigate and report them, and FoodNet to track general trends and define where more effective prevention strategies are needed.

These networks stand prepared to detect a public health event related to the food supply. For example, after investigations of PulseNet-identified clusters of *E. coli* infection focused attention on the need for specific controls during ground beef processing, regulatory and industry practices changed in 2002, and the incidence of *E. coli* O157 infections began to decrease sharply. By 2005, the incidence of *E. coli* O157 infections as measured in FoodNet had dropped 29% since the baseline period of 1996–1998, which very nearly met the goal for Healthy People 2010. During the same time period, the occurrence of *Listeria* infections decreased by 32%.

In 2000, in collaboration with FDA and eight states (California, Colorado, Connecticut, Georgia, Minnesota, New York, Oregon, and Tennessee), CDC established the Environmental Health Specialists Network (EHS-Net). The purpose of EHS-Net is to assist state health departments in their efforts to improve the practice of environmental health service programs. EHS-Net is a collaborative forum of environmental health specialists (EHSs), epidemiologists, and laboratorians who work to identify and prevent environmental factors contributing to foodborne and waterborne disease outbreaks.

EHS-Net has been instrumental in characterizing policies and practices of retail foodservice establishments associated with foodborne outbreaks. For instance, a recent EHS-Net study found that food safety certification of kitchen managers in restaurants appears to be an important foodborne outbreak prevention measure. The EHS-Net also studies policies and practices of retail foodservice establishments in handling specific foods that have been associated with past foodborne outbreaks. Studies such as these provide regulators with the science-based practical research necessary for adopting recommended practices and for developing new or evaluating existing foodborne disease prevention measures.

CDC Goals

CDC is adapting to meet twenty-first century health and safety threats. New strategies, innovations, and goals bring new focus to the agency's work, allowing CDC to do even more to protect and improve health. CDC has developed four major overarching goals, all of which specifically involve foodborne illness related activities: Healthy People in Every Stage of Life, Healthy People in Healthy Places, Healthy People in a Healthy World, and People Prepared for Emerging Health Threats. In addition to the efforts previously described, activities that contribute to these overarching goals include working with physicians and clinical labs to promote proper diagnosis and treatment; educating consumers and promoting safe food practices in homes, restaurants, and institutions; monitoring antimicrobial resistance among microbes that can cause foodborne illness; and enhancing public health networks to detect and respond to outbreaks faster.

CDC's Role in the Recent *E. coli* Outbreak Related to Spinach

On Friday, September 8, 2006, CDC officials were alerted by epidemiologists in Wisconsin of a small cluster of *E. coli* serotype O157:H7 infections of unknown source. Wisconsin also posted the “DNA Fingerprint” pattern of the cluster to PulseNet, thus alerting the entire network. Separately, the state health department of Oregon also noted a very small cluster of infections that day and began interviewing the cases. On September 13, both Wisconsin and Oregon reported to CDC that initial interviews suggested that eating fresh spinach was commonly reported by cases in both clusters of *E. coli* serotype O157:H7 infections in those states. PulseNet showed that the patterns in the two clusters were identical, and other states reported cases with the same PulseNet pattern among ill persons who also had eaten fresh spinach. CDC notified FDA about the Wisconsin and Oregon cases and the possible link with bagged fresh spinach. CDC and FDA convened a conference call on September 14 to discuss the outbreak with the states.

Quick sharing of information among the states, CDC, and FDA led to FDA warning the public on September 14 not to eat fresh bagged spinach. On September 15, as the number of reported cases approached 100, CDC activated its Director's Emergency Operations Center (DEOC), which provided a facility conducive to an intensive team effort. Working in the DEOC improved coordination for daily inter-agency calls, for numerous calls among FDA, CDC, and the states, and for communication activities.

The epidemiological phase of the *E. coli* O157 outbreak response was composed principally of CDC and state PulseNet and OutbreakNet Team members. Cases were identified by PulseNet and interviewed in detail by members of OutbreakNet. Leftover spinach was cultured at CDC, FDA, and in state public health laboratories. CDC and FDA also collaborated on updated analytical methods and provided reagents to state laboratories. The epidemiologic investigation indicated that the outbreak was associated with bagged spinach produced under multiple labels in a single plant on a single day during a single shift. CDC also worked with teams in Wisconsin, Utah, and New Mexico to conduct a formal case-control study, which was useful in confirming that the risk was associated with one processing plant.

Coordination with FDA was essential for investigating the outbreak. Frequent conference calls relayed the data on spinach purchases and sources to FDA, guiding the ongoing investigation of possible production sites of interest. At FDA's request, an experienced hydrologist from CDC's National Center for Environmental Health was deployed to California to join FDA and the California Food Emergency Response Team in the investigation of possible environmental sources of contamination that led to this outbreak. To ensure that information was disseminated to the public as accurately and quickly as possible about health threats and other information related to this outbreak, CDC and FDA coordinated their communication strategies and messages and discussed these strategies in daily calls with state health officials. CDC utilized its Emergency Communication System, part of its DEOC, to coordinate internal and external communications, such as press releases, teleconferences, and web postings.

CDC also provided information via the Health Alert Network (HAN) Messaging System, disseminating updates directly or indirectly to over 1 million individuals including state and local health officers, public information officers, and others.

CDC's daily posting of case updates ended on October 6 when it was clear that the outbreak was over, although PulseNet continues to monitor the frequency of this pattern among all diagnosed *E. coli* O157 infections. Between August 1 and October 6, a total of 199 persons infected with the outbreak strain of *E. coli* O157:H7 were reported to CDC from 26 states. Among the ill persons, 102 were hospitalized, 31 had hemolytic uremic syndrome which can lead to kidney failure (HUS), and three persons died. Eighty-five percent of patients reported illness onset from August 19 to September 5. Among the 130 patients for which a food consumption history was collected, 123 (95%) reported consuming uncooked fresh spinach during the 10 days before illness onset. In addition, *E. coli* O157:H7 with a DNA "fingerprint" pattern matching the outbreak strain was isolated from 11 open packages of fresh spinach that had been partially consumed by patients.

For this investigation, a confirmed case was defined as a culture-confirmed *E. coli* O157:H7 infection in a person residing in the United States, with illness onset from August 1 to October 6 (or, if date of onset was unknown, *E. coli* O157:H7 isolated from August 1 to October 6) and a PulseNet "fingerprint" pattern identified by the *Xba*I restriction enzyme that matched the pattern of the outbreak strain. August 1 was selected as the earliest illness onset date in the case definition to ensure that the earliest cases in the outbreak were identified and investigated. However, the first six

confirmed cases (with illness onsets during August 2–15) were in persons who did not report eating fresh spinach during the week before illness onset. The first person who reported recently eating fresh spinach and had infection with the outbreak strain fell ill on August 19. Thus, August 19 marked the effective beginning of the outbreak.

This outbreak strain of *E. coli* O157:H7 is one of 3,520 different *E. coli* O157:H7 patterns reported to CDC PulseNet since 1996. Infections with this strain have been reported sporadically to CDC's PulseNet since 2003, at an average of 21 cases per year from 2003 to 2005. This finding suggests that this strain has been present in the environment and food supply occasionally, although it had not been associated with a recognized outbreak in the past.

The time from illness onset to confirmation that a case of *E. coli* O157:H7 is part of an outbreak is typically 2–3 weeks, including the time required for an infected person to seek medical care, for health-care providers to obtain a diagnostic culture, transfer the bacterial strain to a public health laboratory, perform “DNA fingerprinting”, and submit the “fingerprint” pattern into the national PulseNet database at CDC. In this outbreak, the average time from illness onset to DNA pattern submission to the national database at CDC was 15 days.

Parallel laboratory and epidemiologic investigations were crucial in identifying the source of this outbreak. Timely PulseNet “fingerprinting” by state public health laboratories, “fingerprint” pattern submission by states to the PulseNet database at CDC, and analysis of “fingerprint” patterns in the CDC PulseNet national database

resulted in rapid detection of the outbreak. Rapid collection of standard case exposure information by OutbreakNet epidemiologists in affected states and sharing of exposure information among states and CDC led to rapid identification of the suspected food source and public health action.

Collaborations with Food Safety Partners

Council to Improve Foodborne Outbreak Response

The epidemiology of foodborne and diarrheal diseases is always changing, the result of changing diagnostic and subtyping capabilities in laboratories, newly recognized and emerging pathogens, changes in food production, distribution, processing, and consumption patterns, demographic shifts, and many other factors. To successfully manage foodborne outbreak challenges, public health agencies must constantly adapt. The Council to Improve Foodborne Outbreak Response (CIFOR) was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. CIFOR's agenda includes improving the performance and coordination of relevant local, state, and federal public health agencies involved in epidemiology, environmental health, laboratory sciences, and regulatory affairs.

CIFOR, co-chaired by the Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO), will develop multi-state outbreak guidelines, a repository for resources and tools, and performance measures for response to enteric illness. CIFOR includes representatives from CDC, FDA, USDA, CSTE, NACCHO, APHL, the Association of State and Territorial Health

Officials, National Environmental Health Association, and the Association of Food and Drug Officials.

Council of Association Presidents

Integrating the food safety and food defense efforts of Federal, state, and local public health, veterinary and food safety officials is of critical importance. CDC is collaborating with FDA, USDA, and the Council of Association Presidents to raise awareness of current and emerging issues and to promote coordination. The Council comprises the ten leading public health, veterinary, and food safety associations that work the spectrum of food safety and food defense, from animal feed to human health. The collective expertise and collaboration of these associations are essential to develop and implement integrated efforts, provide needed training, and build the multi-disciplinary capacity necessary to address food-related emergencies.

Conclusion

The recent outbreak of *E. coli* O157 infections related to spinach was large and deadly. Although the overall number of infections caused by this organism has decreased in recent years as the safety of meat has improved, this outbreak illustrates that better control and prevention measures are needed in other sectors of the food industry before we can consider *E. coli* O157 under adequate control. Although spinach has not been a source of *E. coli* O157 outbreaks before, lettuce has been implicated on several occasions. In fact, there have been twenty outbreaks involving leafy greens, seven of

which were traced to California. A better understanding is needed of the mechanisms by which leafy greens become contaminated so contamination can be interrupted.

The event illustrates how a large and widespread outbreak can occur, appearing first as small clusters, and then rapidly increasing if a popular commercial product is contaminated. It also illustrates the importance of existing public health networks: the laboratories performing PulseNet “fingerprinting”; the epidemiologists interviewing patients and healthy people and collecting leftover spinach; the multi-disciplinary approach to the investigation; and the close communication and collaboration among local, state, and federal officials. This investigation illustrates what a robust public health system can do and lays down a benchmark for the future. Without question, a rapid and accurate analysis of and response to an outbreak will result in prevention of exposure to contaminated products and will stop further illness and death.

Produce-related outbreaks are a growing challenge to public health. As this and other outbreaks indicate, research should focus on tracing the specific pathways that connect fields of leafy green vegetables with potential animal reservoirs of *E. coli* and other disease-causing microbes. CDC is prepared to continue working with regulatory authorities, food and environmental microbiologist scientists, and the food industry to find long-term solutions to this challenging problem.